The Amendments to the Claims

Claims 2, 15, 19, 59, and 63 have been amended to depend on claims 1, 14, 18, 58, and 60, respectively. Claims 3, 16, and 20 have been amended to depend on claims 2, 15, and 19, respectively. Claims 9, 10, 26, 27, 39-56, 64, and 65 have been cancelled. No new matter has been added by way of these amendments.

Accordingly, claims 1-5, 8, 11-22, 25, 28-38, 57-63 are pending, wherein claims 1-5, 8, 11-22, 25, 28-38, 57, and 60-63 have been withdrawn from consideration.

Examiner Interview

Applicants wish to thank Examiners Duffy and Blanchard for the telephonic interview which took place on October 5, 2006, with Julie Hong. The restriction of the members of the Markush group of claims 8, 9, 35, and 57 into separate groups, as opposed to an election of species, was discussed. No agreement was reached.

Discussion of the Restriction Requirement

In reply to the Office Action mailed September 18, 2006, in the referenced patent application, Applicants respectfully traverse the restriction requirement for the reasons set forth below.

As a first matter, because the instant application is a national stage application under 35 USC 371, the inclusion of more than one invention is permitted if all inventions are so linked as to form a single general inventive concept (MPEP § 1893.03(d)). Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. "Special technical features," as defined by PCT Rule 13.2, refers to those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

In the instant case, the special technical feature of the invention of claims 58 and 59 is a method for inducing apoptosis of a natural killer (NK) cell, comprising contacting the NK

cell with an amount of an IL-21 polypeptide, either through administration of an IL-21 polypeptide or by administering a polynucleotide encoding an IL-21 polypeptide. As such, at the very least, groups XXII and XXIII should be examined together.

The Office Action contends that there is no special technical feature that defines a contribution over the prior art, since WO 99/61617 (Ruben et al.) allegedly discloses the administration of IL-21 polypeptides to patients to treat hyperproliferative disorders. WO 99/61617 is a non-enabling reference, as there is no data to support that administration of IL-21 polypeptides would actually treat cancer.

In view of the foregoing, at least claims 58 and 59 are linked by a single inventive concept that is not disclosed by the prior art.

As a second matter, the Office has divided the subject matter of each of claims 8, 9, 35, and 57 into separate groups: claim 8 is divided into Groups III-VI, claim 9 is divided into Groups VII-X, claim 35 is divided into Groups XV-XVIII, and claim 57 is divided into Groups XIX-XXI. Each of claims 8, 9, 25, and 57 is a Markush–type claim directed to the group of elements: a vaccine, an antigen-specific T lymphocyte, a cytokine, or a combination thereof. Section 803.02 of the MPEP states that

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they *>may be< directed to independent and distinct inventions.

In the instant case, the Markush group contains only three members, such that the Office must examine all members on the merits.

Even if the Office takes the position that the Markush-type claim encompasses at least two independent or distinct inventions, the Office is to require a provisional election of species for examination on the merits. See MPEP at Section 803.02 which states

> In an application containing **>a Markush-type claim that encompasses at least two independent or distinct inventions<, the examiner may require a provisional election of a single species prior to examination on the merits.**>"

Furthermore, each of claims 8, 9, 35, and 57 is a dependent claim, such that each is linked to the claim on which it is dependent. The claim on which each is dependent is considered as a generic claim and each of claims 8, 9, 35, and 57 is a species claim. Where an application contains a generic claim and claims to more than one patentably distinct species, an election of species for purposes of search and examination is proper. 37 CFR 1.146

In view of the foregoing, restriction between the members of the Markush group of claims 8, 9, 35, and 57 is not proper.

Moreover, examination of the patent application would be most expeditious by examining all pending claims together. As Section 803 of the MPEP requires,

> If the search and examination of all the claims in an application can be made without serious burden, the Examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

The restriction requirement is improper because the Examiner has not shown that a search and examination of the entire application would, indeed, cause a serious burden, as required by Section 803 of the MPEP for proper restriction. In fact, a serious burden would arise only if examination of the patent application were restricted to one of the claim groups. Filing an additional patent application containing the non-elected claims would unnecessarily burden (1) the Patent and Trademark Office, since it must assume the additional labor involved in examining at least two separate applications; and (2) the public, since it will have to analyze at least two patents (assuming the subject matter of each claim group is found patentable) to ascertain all of the claimed subject matter.

However, to comply with the requirements of the Patent and Trademark Office, Applicants provisionally elect Group XXIII (claim 59) directed to a method for inducing apoptosis of a NK cell comprising contacting the NK cell with an IL-21 polypeptide, variant,

or fragment of either of the foregoing, wherein contacting the NK cell with an IL-21 polypeptide, variant, or fragment of either of the foregoing comprises contacting the NK cell with a polynucleotide encoding the IL-21 polypeptide, variant, or fragment in an amount effective to induce apoptosis of the NK cell.

Conclusion

A favorable action is solicited. The Commissioner is authorized to charge any extension of time fees pursuant to 37 CFR 1.17(a)-(d) associated with this communication and to credit any excess payment to Deposit Account No. 12-1216. A duplicate copy of this Response is attached.

Respectfully submitted,

Jeremy M. Jay, Reg. No. 33,587
LEYDIG, VOIT & MAYER
700 Thirteenth Street, N.W., Suite 300
Washington, DC 20005-3960
(202) 737-6770 (telephone)
(202) 737-6776 (facsimile)

Date: 18 Jan. 2007

M:\clients\NIH\Amd\280591am3-RRR.doc